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AUG 4 1995

Paul Grandinetti
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Washington, D.C. 20006-1401

Re: Patent Term Extension
Application for
U.S. Patent No. 4,976,273

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,976,273 issued December 11, 1990, which claims the medical device REALITY Female Condom, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 719 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 11, 1994. Under 35 U.S.C. § 156(c):

Period of Extension	=	1/2 (Testing Phase) + Approval Phase
	=	1/2 (1,460 - 1,137) + 557
	=	719 days

Since the regulatory review period began October 31, 1987, before the patent issued (December 11, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c) (From October 31, 1987 to December 11, 1990 is 1,137 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 1,460 - 1,137 = 323 days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitations of 35 U.S.C. § 156(g)(6) and the 14 year exception of 35 U.S.C. § 156(c)(3) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

It is noted that applicant has filed another application for patent term extension of U.S. Patent

No. 4,735,621 which is also based upon the regulatory review of the product REALITY Female Condom. No more than one patent may be extended for a regulatory review period of a product. 35 U.S.C. 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (A certificate of extension will be issued to U.S. Patent No. 4,735,621.) In the absence of such request for reconsideration and if U.S. Patent No. 4,976,273 is elected, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,976,273 a certificate of extension, under seal, for a period of 719 days.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,976,273
Granted:	December 11, 1990
Applicant:	Lasse Hassel
Owner of Record:	Chartex International Plc.
Title:	TUBULAR PROTECTIVE DEVICE FOR PROTECTION AGAINST TRANSFER OF INFECTIOUS MATTER DURING SEXUAL INTERCOURSE
Classification:	128/844
Product Trade Name:	REALITY

Term Extended: 719 days

Gerald A. Dost

Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: REALITY
FDA Docket No.: 93E-0268